



AMERICAN VETERINARY MEDICAL ASSOCIATION

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Animal Drug Availability Act; Veterinary Feed Directive (Docket No. 99N-1591)

Dear Sir or Madam:

The American Veterinary Medical Association, on behalf of its 63,000 members, wishes to comment on the proposed rule to implement the Veterinary Feed Directive drugs section of the Animal Drug Availability Act. The Association is the authorized voice for the profession in presenting its views to government, academia, agriculture, pet owners, the media, and other concerned publics. The objective of the AVMA is to advance the science and art of veterinary medicine, including its relationship to public health, biological science, and agriculture.

The AVMA supports the VFD as a means to enhance the availability of medicated feeds to alleviate animal suffering and death. We applaud the FDA's recognition of the veterinarian as "the critical aspect of the system" involved in "the selection and use of the VFD drug." The AVMA strongly supports the comments of the American Association of Swine Practitioners, the association of veterinarians that has had the most experience with the one approved VFD drug.

The AVMA encourages the FDA to remain flexible and to defer to the veterinarian's professional judgement on issues of VFD expiration dates and numbers of refills/reorders. Such decisions constitute the practice of veterinary medicine. Flexibility is needed to allow for the practical application of the VFD to various types of production systems, and to address the application of the VFD to different groups of animals coming through a specific stage of production at a given facility, when appropriate. This should not be misconstrued as support of the continual use of a VFD drug in the same animals. Additionally, label directions must be followed carefully by all involved in the use of VFD products. The AVMA concurs that writing of a VFD shall occur only in the presence of a valid veterinarian-client-patient relationship. As you are aware, veterinarians currently determine the period of treatment and number of refills for patients receiving dosage form prescription drugs. By natural extension, this same latitude should be granted to veterinarians to maximize their ability to prevent animal suffering and death. Veterinarians should be able to use their education, skills, and experience to make custom recommendations for a given

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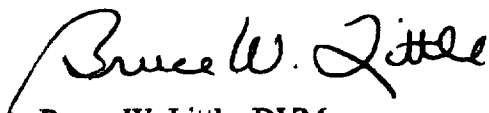
client. The concept of the FDA determining expiry dates and whether refills/reorders are allowed is not in the patients' best interest and is therefore not tolerable.

The AVMA supports the use of fax orders made by the veterinarian to the distributor or client for VFD drugs, followed by a forwarded written and signed VFD. In addition, we support use of both telephone and e-mail as means to initiate a VFD order. Again, there is precedence for telephone orders in veterinary medicine. Pharmacists currently reduce oral telephone prescription orders to writing and dispense prescription drugs on the basis of that communication. Even telephone orders for controlled substances in schedules III-V are reduced to writing by pharmacists and dispensed, without receipt of any written order. Security is managed by use of the veterinarian's license number for prescription drugs, and DEA registration number for the above mentioned controlled substances.

The AVMA believes that provision of an e-mail order with inclusion of the veterinarian's license number is quite acceptable. In all these methods of initiating an order, the FDA is providing a second layer of security by requiring the prompt provision of the written, signed VFD by the veterinarian. The AVMA asks that the final rule contain the word "promptly" rather than "immediately" when referring to the forwarding of a written and signed VFD to follow these other methods of order initiation. Additionally, VFD medicated feeds should be made available to the client (animal producer) on the basis of the fax, telephone or e-mail order, i.e. the client should not be required to wait for the signed and written form to be received by the distributor before receiving the VFD medicated feed.

We are appreciative of this opportunity to comment and look forward to the availability of additional VFD products to reduce animal suffering and death.

Respectfully,



Bruce W. Little, DVM
Executive Vice President

BWL/ECG